

**68-9-3. Automated drug delivery system for distribution of drugs.** (a) For purposes of this regulation "automated drug delivery system" means a robotic, mechanical or computerized device that is used for supplying drugs for administration in a medical care facility as defined in K.S.A. 65-425, an institutional drug room as defined in K.S.A. 65-1626, or a long term care facility which means a nursing facility as defined in K.S.A. 39-923.

(b) A managing pharmacy located in Kansas shall provide the board with prior written notice of the installation of an automated drug delivery system on a form provided by the board or upon the removal of any system and ensure that all necessary licenses, registrations, and authorizations have been obtained prior to engaging the use or stocking of an automated drug delivery system including a drug enforcement administration permit for supplying controlled substances.

(c) The pharmacist-in-charge of the managing pharmacy shall be responsible for the following:

- (1) Maintaining a record of each transaction or operation;
- (2) controlling access to the automated drug delivery system; and
- (3) maintaining policies and procedures for:
  - (A) Operating the automated drug delivery system;
  - (B) preapproval and training of personnel who are authorized to remove any drug and maintain, at the location of the automated drug delivery system, a list of those individuals;
  - (C) maintaining patient services whenever the automated drug delivery system is not operating;

(D) defining a procedure for a pharmacist to grant access to the drugs in the automated drug delivery system or to deny access to the drugs in the automated drug delivery system.

(4) securing the automated drug delivery system;

(5) assuring that a patient receives the pharmacy services necessary for appropriate pharmaceutical care;

(6) assuring that the automated drug delivery system maintains the integrity of the information in the system and protects patient confidentiality;

(7) establishing a procedure for stocking and restocking the automated drug delivery system;

(8) ensuring compliance with all requirements for packaging and labeling medications pursuant to K.A.R. 68-7-15 and K.A.R. 68-7-16 or package in a manufacturer's sealed original package or in repackaged containers.

(9) ensuring preventive maintenance and sanitation of the automated drug delivery system; and

(10) ensuring that the automated drug delivery system has a mechanism for securing and accounting for drugs removed from and subsequently returned to the system;

(11) ensuring that there is a policy in place for securing and accounting for wasted or discarded drugs;

(12) ensuring preventive maintenance and sanitation of the automated drug delivery system;

(13) ensuring that inspections are conducted and documented at least monthly to ensure accuracy of contents;

(14) ensuring the accurate stocking and restocking of automated drug delivery system by approving and implementing an operational policy that limits the personnel responsible for the loading and unloading of the automated drug delivery system to a Kansas-licensed pharmacist or either of the following, each of whom shall be under the pharmacist's supervision:

(A) a Kansas registered pharmacy intern; or

(B) a Kansas registered pharmacy technician;

(d) A pharmacist shall perform prospective drug use review and approve each medication order prior to the administration of a drug except an override or a physician controlled medication.

(e) A pharmacist shall perform retrospective drug use review for an override medication.

(f) The pharmacist-in-charge shall consult with the pharmacy and therapeutics committee or an equivalent committee in establishing the criteria and process for determining which drugs qualify as an override medication.

(g) The managing pharmacy shall review emergency medication orders and discrepancies or transaction reports within 72 hours.

(h) A pharmacy utilizing an automated drug delivery system may distribute patient-specific drugs without verifying each individual drug selected or packaged by the system, if;

(1) The initial medication order has been reviewed and approved by a pharmacist; and

(2) The drug is distributed for subsequent administration by a health care professional permitted by Kansas law to administer drugs.

(i) The pharmacist in charge shall be responsible for establishing a quality assurance program for the automated drug delivery system. The program shall provide for:

(1) Review of override medication utilization;

(2) Investigation of any medication error related to drugs distributed or packaged by the automated drug delivery system;

(3) Review of any discrepancy or transaction reports and identification of patterns of inappropriate use or access of the automated drug delivery system;

(4) review of the operation of the automated drug delivery system;

(5) integration of the automated drug delivery system quality assurance program with the overall continuous quality improvement program of the pharmacy or risk management program of a hospital;

(6) assurance that individuals working with the automated drug delivery system receive appropriate training on operation of the system and procedures for maintaining pharmacy services when the system is not in operation.

(k) The pharmacist-in-charge shall maintain for at least five years the following records related to the automated drug delivery system in a readily retrievable manner;

(1) Transaction records for all non-controlled drugs or devices distributed by the automated drug delivery system;

(2) transaction records from the automated drug delivery system for all controlled substances distributed; and

(3) any report or analysis generated as part of the quality improvement program required by paragraph () of this rule.

(l) A pharmacist shall conduct and document a daily audit of the drugs placed or to be placed into an automated drug delivery system by a pharmacy intern or pharmacy technician, which audit may include random sampling;

(m) A bar code verification, electronic verification, or similar verification process shall be utilized to assure correct selection of drugs placed or to be placed into an automated drug delivery system. The utilization of a bar code, electronic or similar verification process shall require an initial quality assurance validation, followed by a quarterly assurance review by a pharmacist. When a bar code verification, electronic verification, or similar verification process is utilized as specified in this section, stocking and restocking functions may be performed by a pharmacy technician, pharmacy intern, or a registered nurse trained and authorized by the pharmacist-in-charge.

(n) The pharmacist performing the quality assurance review shall maintain a record of the quality assurance process that occurred and the pharmacist approval of the drug stocking, restocking or verification process.

(o) Any drug that has been removed from the automated drug delivery system shall not be replaced into the system unless:

(1) the drug's purity, packaging, and labeling have been examined according to policies and procedures established by the pharmacist-in-charge to determine the reuse of the drug is appropriate; or

(2) specific drugs, such as multi-dose vials, have been exempted by the pharmacy and therapeutics committee or an equivalent committee. (Authorized by K.S.A. 65-1630; implementing K.S.A. 2013 Supp. 65-1626 and K.S.A. 65-1648; effective P-\_\_\_\_\_.)

